Atty Dkt No: PP19199.002 USSN: 10/658,782

**PATENT** 

## **AMENDMENT**

## In the Claims:

The following listing reflects amendments to the claims and replaces all prior versions and listings of claims in this application.

- 1. (Cancelled)
- 2. (Cancelled)
- 3. (Currently amended) A method of detecting hepatitis C virus (HCV) infection in a biological sample, said method comprising:
- (a) providing an immunoassay solid support comprising HCV antigens bound thereto, wherein the HCV antigens consist of one or more HCV NS3/4a antigens wherein at least one of the NS3/4a antigens comprises comprises comprises a conformational epitope and comprises, wherein the NS3/4a antigen has an amino acid sequence with at least 80% sequence identity to the contiguous amino acid sequence amino acids 2-686 of SEQ ID NO:2;
- (b) combining a biological sample with said solid support under conditions which allow HCV antibodies, when present in the biological sample, to bind to said one or more NS3/4a antigens;
- (c) adding to the solid support from step (b) under complex-forming conditions a detectably labeled HCV multiple epitope fusion antigen (MEFA), wherein said labeled MEFA comprises at least one epitope from the HCV NS3/4a region and a consensus sequence from the E2 hypervariable region spanning amino acids 390-410 with the sequence of SEQ ID NO:7, numbered relative to the HCV-1 polyprotein sequence, wherein said MEFA binds said bound HCV antibody;
- (d) detecting complexes formed between said HCV antibody and said NS3/4a antigen and said MEFA, if any, as an indication of HCV infection in the biological sample.

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4. (Cancelled)

5. (Cancelled).

6. (Currently amended) The method of claim 3, wherein at least one of said NS3/4a antigens consists of the amino acid sequence of SEQ ID NO:2.

- 7. (Original) The method of claim 3, wherein said MEFA comprises an epitope from the NS3/4a protease region of the HCV polyprotein.
- 8. (Original) The method of claim 3, wherein said MEFA comprises an epitope from the NS3/4a helicase region of the HCV polyprotein.
- 9. (Original) The method of claim 8, wherein said MEFA comprises amino acids 1193-1657, numbered relative to the HCV-1 sequence.
- 10. (Original) The method of claim 3, wherein said MEFA comprises an epitope from the c33c region of the HCV polyprotein.
- 11. (Original) The method of claim 10, wherein said MEFA comprises amino acids 1211-1457, numbered relative to HCV-1.
- 12. (Original) The method of claim 10, wherein said MEFA comprises amino acids 1192-1457, numbered relative to HCV-1.
- 13. (Original) The method of claim 3, wherein said MEFA comprises an epitope from the 5-1-1 region of the HCV polyprotein.
- 14. (Original) The method of claim 13, wherein said MEFA comprises amino acids 1689-1735, numbered relative to HCV-1.

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15. (Previously presented) The method of claim 3, wherein said MEFA comprises the amino acid sequence of SEQ ID NO:4.

- 16. (Previously presented) The method of claim 3, wherein said MEFA comprises the amino acid sequence of SEQ ID NO:6.
  - 17. (Cancelled)
  - 18. (Cancelled)
- 19. (Currently amended) A method of detecting hepatitis C virus (HCV) infection in a biological sample, said method comprising:
- (a) providing an immunoassay solid support comprising HCV antigens bound thereto, wherein the HCV antigens consist of one or more multiple epitope fusion antigens (MEFAs) wherein said one or more MEFAs comprise at least one epitope from the HCV NS3/4a region and a consensus sequence from the E2 hypervariable region spanning amino acids 390-410 with the sequence of SEQ ID NO:7, numbered relative to the HCV-1 polyprotein sequence;
- (b) combining a biological sample with said solid support under conditions which allow HCV antibodies, when present in the biological sample, to bind to said one or more MEFAs;
- (c) adding to the solid support from step (b) under complex-forming conditions a detectably labeled HCV NS3/4a antigen comprising a conformational epitope, wherein said detectably labeled NS3/4a antigen binds said bound HCV antibody, and further wherein said NS3/4a antigen has an amino acid sequence with at least 80% sequence identity to the contiguous amino acid sequence amino acids 2-686 of SEQ ID NO:2;
- (d) detecting complexes formed between said HCV antibody and said detectably labeled NS3/4a antigen and said MEFA, if any, as an indication of HCV infection in the biological sample.
  - 20. (Cancelled)

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21. (Cancelled)

22. (Previously presented) The method of claim 19, wherein said detectably labeled

NS3/4a antigen consists of a detectable label and the amino acid sequence of SEQ ID NO:2.

23. (Original) The method of claim 19, wherein said MEFA comprises an epitope from

the NS3/4a protease region of the HCV polyprotein.

24. (Original) The method of claim 19, wherein said MEFA comprises an epitope from

the NS3/4a helicase region of the HCV polyprotein.

25. (Original) The method of claim 24, wherein said MEFA comprises amino acids

1193-1657, numbered relative to the HCV-1 sequence.

26. (Original) The method of claim 19, wherein said MEFA comprises an epitope from

the c33c region of the HCV polyprotein.

27. (Original) The method of claim 26, wherein said MEFA comprises amino acids

1211-1457, numbered relative to HCV-1.

28. (Original) The method of claim 26, wherein said MEFA comprises amino acids

1192-1457, numbered relative to HCV-1.

29. (Original) The method of claim 19, wherein said MEFA comprises an epitope from

the 5-1-1 region of the HCV polyprotein.

30. (Original) The method of claim 29, wherein said MEFA comprises amino acids

1689-1735, numbered relative to HCV-1.

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31. (Previously presented) The method of claim 19, wherein said MEFA comprises the amino acid sequence of SEQ ID NO:4.

- 32. (Previously presented) The method of claim 19, wherein said MEFA comprises the amino acid sequence of SEQ ID NO:6.
- 33. (Withdrawn) The method of claim 3, wherein said MEFA is MEFA 13 or MEFA 13.1.
- 34. (Withdrawn) The method of claim 19, wherein said MEFA is MEFA 13 or MEFA 13.1.